HIMA
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

September 7, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99D-1273; Draft Guidance for FDA Staff on Civil Money Penalty Policy; Comments of Health Industry Manufacturers Association

Dear Sir or Madam:

The Health Industry Manufacturers Association (HIMA) hereby submits its written comments on the draft guidance entitled "Guidance for FDA Staff on Civil Money Penalty Policy" (Draft Guidance). The notice of the Draft Guidance's availability was published in the *Federal Register*. See 64 Fed. Reg. 30527 (June 8, 1999).

HIMA is the largest medical technology trade association in the world. It has more than 800 member firms that manufacture medical devices, diagnostic products and health information systems. HIMA members provide nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased annually around the world.

HIMA members are regulated by the Food and Drug Administration (FDA) under the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). Since civil money penalties (CMP) are one of the enforcement remedies that the FDA is authorized to use for FFDCA violations pertaining to medical devices, HIMA members are directly affected by the FDA's policies for using this remedy. Below HIMA provides its comments on the Draft Guidance.

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General Comments on the Organization and Clarity in the Draft Guidance

The Draft Guidance consists of three separate documents: the "Safe Medical Devices Act Civil Money Penalty Decision Tree" (hereafter, the "Decision Tree document"), consisting of 8 pages and a flow chart; the "Application of the Safe Medical Devices Act Civil Money Penalty Policy" (hereafter, the "Application document"), consisting of 5 pages; and the "Safe Medical Devices Act Civil Money Penalty Fee Matrix" (hereafter, the "Fee Matrix document"), consisting of 4 pages.

As a general matter, HIMA is concerned that readers of the Draft Guidance may find it confusing. The fact that there are three separate documents in the Draft Guidance is one feature that contributes to the lack of clarity. HIMA can understand the logic of having a separate Fee Matrix document, but sees no reason why the Decision Tree and Application documents could not have been combined for the sake of simplicity. The subject matter in these two documents overlaps and having two separate documents discussing related topics could confuse the reader.

Moreover, the Draft Guidance fails to provide clearly-articulated standards to which FDA staff can refer in making a choice between a civil penalty or other enforcement action. Throughout the text of the Application and Decision Tree documents and the Decision Tree flow chart, the FDA makes various partial suggestions for and observations about the appropriate use of civil penalties versus other remedies. The decentralized fashion of the guidance makes it hard for the reader to follow. There is no single portion of the Draft Guidance that pulls together all of the FDA's thoughts on the subject. As such, the present Draft Guidance has the potential for confusing the FDA staff when it decides on a civil penalty versus other enforcement remedies.

To illustrate, in seeking an answer to the question, "When are civil penalties appropriate?", the reader has to track down various pieces of guidance in many different places in the Draft Guidance. Some of these places are discussed below:

1. The opening paragraph of the GMP section on page 2 of the Application document states, "CMP actions should be considered for those situations in which a firm continues to violate the GMP regulations, there is a reasonable probability that the firm will likely produce nonconforming and/or defective finished devices, and seizure or injunction is not appropriate or necessary to bring about corrective action." (Emphasis added.) This statement implies that there are some situations of this type in which seizure and/or injunction are appropriate and others where they are not. Yet there is no guidance on which situations fall into each category.

2. At the bottom of page 4 of the Application document, under the heading "Seizures/Injunctions Not Appropriate," the advice given is overly brief, unclear, and only by way of example:

> CMP may be appropriate in situations where seizures or injunctions were not the action of choice (provided evidence of the violation is clear) or where it has been determined that seizure or injunction is simply not appropriate (i.e. insufficient product available for seizure; evidence too old for injunction).

In this section FDA should mention that Agency officials, before instituting civil penalty actions, should not only consider the appropriateness of seizure and injunction actions, but should also consider the appropriateness of the regulatory actions authorized by Section 518 of the FFDCA such as notification, repair, replacement, refund, reimbursement, and recall.

This section should go on to state that the application of enforcement actions should be progressive, i.e. the lowest level of appropriate enforcement actions should be utilized to achieve compliance. This should be followed when necessary by increasing levels of enforcement for repeated violations. The first level of enforcement should consist of notification of the deficiencies and the opportunity to correct them through voluntary compliance.

3. In the second and concluding paragraph of this same section, at the top of page 5 of the Application document, only brief, isolated examples (as opposed to workable criteria) are given for cases where CMPs "may be considered" because "seizure or injunction would not normally be the action of choice." The only examples given are "promotion and advertising violations, failure of sponsors to meet IDE reporting requirements, or failure of clinical investigators to submit completed case reports."

As stated above, in this section FDA should mention that Agency officials, before instituting civil penalty actions, should not only consider the appropriateness of seizure and injunction actions, but should also consider the appropriateness of the regulatory actions authorized by Section 518 of the FFDCA such as notification, repair, replacement, refund, reimbursement, and recall.

This section should go on to state that the application of enforcement actions should be progressive, i.e. the lowest level of appropriate enforcement actions should be utilized to achieve compliance. This should be followed when necessary by increasing levels of enforcement for repeated violations. The first level of enforcement should consist of notification of the deficiencies and the opportunity to correct them through voluntary compliance.

4. In the following two sections on page 5 of the Application document, entitled "Problems with Low Risk Devices" and "Less Significant Violations," there is guidance that CMPs should be considered for violations involving "low risk devices" and for "less significant violations." This guidance again amounts to overly general treatment of the subject of choice of remedy. No attempt is made here to provide a more comprehensive overview of the considerations and

factors impacting upon choice of remedy. It also does not define "low risk devices" or "less significant violations."

As stated above, in this section FDA should mention that Agency officials, before instituting civil penalty actions, should not only consider the appropriateness of seizure and injunction actions, but should also consider the appropriateness of the regulatory actions authorized by Section 518 of the FFDCA such as notification, repair, replacement, refund, reimbursement, and recall.

This section should go on to state that the application of enforcement actions should be progressive, i.e. the lowest level of appropriate enforcement actions should be utilized to achieve compliance. This should be followed when necessary by increasing levels of enforcement for repeated violations. The first level of enforcement should consist of notification of the deficiencies and the opportunity to correct them through voluntary compliance.

5. In the Decision Tree document, at pages 2-3, the guidance attempts to address which regulatory option should be used in particular cases. Again, the guidance here is not detailed or comprehensive. Referring to the Decision Tree flow chart, the text on page 2 says, "At the bottom of the tree, there are examples of situations in which CMP may be particularly helpful." However, the examples at the bottom of the Decision Tree flow chart are short and very limited:

> Consider some of the following examples of where CMPs can apply: second inspection with documented Situation I GMP or chronic violations, failure to [sic] 510(k), or promotion/advertising violations.

6. Finally, there are two boxes at the top of the Decision Tree flow chart, entitled "May other action be necessary or appropriate at this time?" and "Consider appropriate action." They also attempt to deal with the question of which remedy should be chosen. However, they do not clearly establish the connection between particular situations and particular remedies and fail to provide a comprehensive explanation of criteria for choosing remedies.

In short, the Draft Guidance's discussion of the appropriateness of a civil penalty, versus another enforcement action, is decentralized, and the guidance given is very general or only by way of limited and brief examples. HIMA believes the Draft Guidance should provide a comprehensive overview of and criteria for the situations where civil money penalties are appropriate as compared to other enforcement remedies.

Specific Comments on the Decision Tree Document

A. The General Philosophy Should Limit the Use of Civil Penalties to be a Remedial Action Toward a Particular Firm

The Decision Tree document, at page 1, states, "CMP is considered to be a remedial action, not punitive." This means it is designed to influence future conduct of the affected firm and/or other firms that are similarly situated, either directly, by affecting current violative conduct, or indirectly, by serving to deter future conduct. The philosophy expressed by this statement has the potential for the FDA to exercise its discretion in inequitable manner. The FDA in an attempt to influence other firms may take remedial action against firms with a recognizable name, size or presence. The document needs to include safeguards to prevent the FDA from taking action in this manner.

B. Some Examples of What Would Constitute "Prior Warning" Are Inappropriate

The Decision Tree Document, at page 2 states that in general a CMP may be considered in cases where "[o]ther regulatory action is NOT appropriate," "[p]rior warning has been given," and "FDA policy is clear." HIMA is concerned with many of the examples, on page 3 of the Decision Tree document regarding what constitutes "prior warning."

Example (a) is a "Warning Letter, civil suit, administrative action, or other regulatory correspondence." (Emphasis added.) "Other regulatory correspondence" is overly broad and needs to be limited to specific types of correspondence. The correspondence should be limited to a postinspectional notification letter or an untitled letter.

Example (b) is "Notification by state, municipal, or federal agencies involving the same or similar violations." Notification by other state and municipal authorities is not sufficient unless such notice has the same procedural controls as the FDA and such notice discusses the possibility of CMP if the company fails to come into compliance.

Example (c) is an FDA investigator providing a Form FDA-483 (List of Inspectional Observations) at the conclusion of an inspection. Example (d) is an FDA investigator having a "[d]iscussion of objectionable conditions" with a responsible individual of the firm where these conditions "have been documented in the establishment inspection report." Example (e) is "[v]erbal notification from Agency officials to a firm's top management, e.g., in meetings or telephone conversations confirmed in writing." Example (f) is "[w]ritten or oral advisory communication by FDA Center personnel involving critical scientific issues."

Regarding Examples (c) and (d), the Agency itself does not consider a Form FDA-483, or an investigator's discussion of it or other observations with an inspected firm's representatives, as

an Agency notice of violation. The FDA Investigations Operations Manual (IOM) clearly instructs:

> After completion of the inspection, meet with the highest ranking management official possible (owner, operator, or agent in charge) to discuss your findings and observations. The FDA-483 is not a substitute for such discussion since there may be additional questionable practices or areas not appropriate for listing on this form. All discussions will be reported in the EIR, whether or not related to FDA-483 items. . . .
>
> Advise management that you are not the final authority if charges of violations of the law will be brought against them; however, in your opinion the conditions you observed MAY be determined by the FDA after review of all the facts, to be violations. (Emphasis added.) IOM Section 516.

Since the Agency clearly takes the position that an FDA investigator's verbal and written observations are not Agency positions, the FDA should not claim an investigator's Form FDA-483 observations or meeting comments constitute "prior warning" that could lead to a future civil penalty.

Before implementing a CMP program punishing individuals and companies for lack of compliance, the FDA needs to improve the current system which, in certain instances, fails to effectively communicate all instances of noncompliance. Currently it is extremely difficult to obtain copies of Establishment Inspection Reports (EIRs) or information about the Agency's concerns in instances where the investigation is classified as OAI. Therefore, despite the requirement to provide firms with warnings prior to the instigation of CMP actions, firms without the EIR may not have a complete understanding of the FDA's concerns. Additionally, the inability of firms to obtain EIRs or the inspection status in circumstances where the inspection is classified as OAI deters firms from achieving voluntary compliance, an avenue providing greater benefit to the public health than compliance through forced remedial action.

As for Examples (e) and (f), in many cases, these communications may not rise to the level of stating an Agency position. For example, in the FDA's Administrative Practices and Procedures Regulations, 21 C.F.R. Part 10, Section 10.85 states:

> (k) A statement made or advice provided by an FDA employee constitutes an advisory opinion [of the Agency] only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this

> section or § 10.90,[1] is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the Agency to the view expressed. (Emphasis added.)

This regulation illustrates that not all communications by FDA employees represent Agency positions.

As such, Examples (e) and (f) should be clarified to state the communications in question must rise to the level of an Agency position to constitute "prior warning" for civil money penalty purposes. In addition, Example (f) should be limited to written communications. On an unrelated note with respect to Example (f), the term "critical scientific issues" is overly broad and open to many possible interpretations. This concept needs clarification and limitation.

Finally, HIMA believes that the Agency is truly overreaching when it proposes Example (g) as an illustrative "prior warning." Under Example (g), "prior warning" would exist if "pertinent violations" were simply "discussed" at "industry meetings" if "attendance by a firm's representatives is documented." This example could be construed so broadly as to cover a brief mention of a violation in an Agency official's speech to a large industry audience at a conference. While the registration list at a large industry meeting might indicate a firm representative was in attendance, there is no assurance the representative will be in the meeting room at the crucial time and actually hear the reference to a violation. The language of this example does not even specify that the "pertinent violations" be cited with an express warning of enforcement action, but says merely that these "pertinent violations" were "discussed." This example is far too sweeping to constitute a "prior warning." Additionally, in the most egregious case, the language might even be construed to cover situations where the violative conduct was merely brought up at an industry meeting. This is clearly inappropriate.

C. FDA's "Clear Policy" Criterion Should be a "Clear Law" Criterion

On page 4 of the Decision Tree document and in the Decision Tree flow chart itself, the FDA discusses whether a "policy" is "clear" for purposes of a civil money penalty. Unlike statutes and Agency regulations, Agency policies do not have the force and effect of law. Civil penalties should only be imposed for violations of laws where the laws are clear; a civil penalty should never be based on violation of a policy (whether clear or not). For example, the FDA should not impose civil penalties for 510(k) violations under 21 C.F.R. § 807.81(a)(3) (product

[1] Section 10.90 governs the issuance of Agency regulations, guidelines, recommendations and agreements; which is not relevant here.

modifications) because the regulation itself is so nebulous (regardless of existing guidance). This issue also presents itself in the subsection regarding on "Circumstances of the Violations" on page 5 of the Decision Tree document. This subsection refers to "the clarity of applicable statutes, regulations, or policies. . ." (Emphasis added.) HIMA would delete the reference to "policies" in this context.

D. FDA Interpretation of Two of the Statutory Factors Needs Revision

Beginning on page 4 of the Decision Tree document, the text recites the statutory factors in Section 303(f)(3)(B), 21 U.S.C. § 333(f)(3)(B), that the Agency uses in determining the amount of a civil penalty. HIMA has identified two instances where the interpretation of a statutory factor needs revision.

One of the statutory factors, discussed on page 5 of the Decision Tree document, is the "gravity of the violation." The Draft Guidance here instructs the staff to include, in its evaluation of the "gravity," "the amount of Agency or other public resources that were needed to investigate and rectify the violations." HIMA thinks that this "resource" consideration is misplaced in a "gravity" analysis and should, if used, be a completely separate factor of the civil penalty assessment analysis.

Another statutory factor is the history of prior violations, discussed on page 7 of the Decision Tree document. Section 303(f)(3)(B), 21 U.S.C. § 333(f)(3)(B), provides that the FDA is to take into account, among the other statutory factors, "any history of such prior violations." (Emphasis added.) Since the word "such" modifies the word "violations," this arguably indicates that the only prior violations, which Congress intended to be taken into account, were violations of the same type causing civil penalty assessment.

The Draft Guidance adopts a broader interpretation than is warranted by the statute. The Draft Guidance states:

> **History of prior violations** refers to prior conduct of the person that is similar in nature to the violations in the current case; you may consider conduct as similar even if it does not implicate the identical law or regulation . . . . (Emphasis added.)

HIMA believes analysis of prior violations should be limited to those falling under the same statute or regulation; otherwise, FDA staff has too much discretion and no useful guidance in deciding what other statutes or regulations are sufficiently similar. Such a limitation would also be consistent with the language used in Section 303(f)(3)(B).

E. All Section 303(f) Statutory Factors Should be Listed in Decision Tree

Reference is made to the box entitled "Do the statutory factors support the case?" in the Decision Tree flow chart. The box does not give the complete list of statutory factors. HIMA believes it is important to list all of the statutory factors. Therefore, the box in the flow chart should be modified to include the full list of statutory factors.

F. The Draft Guidance Should Avoid the Suggestion of Punitive Civil Penalties

The Draft Guidance claims that a civil penalty is "considered to be a remedial action, not punitive. This means it is designed to influence future conduct of the affected firm and/or other firms . . ., either directly, by affecting current violative conduct, or indirectly, by serving to deter future violative conduct." (Emphasis added.) See Decision Tree document, "General Philosophy," page 1. However, later in the same Decision Tree document, there are two instances where the Draft Guidance could be viewed as almost advising FDA staff to use civil money penalties in a punitive fashion. First, on page 3 of the Decision Tree document, the following statement appears:

> Note that CMP action may be appropriate in situations in which all the violations have been corrected. For example, CMP could be used for a firm that continued to violate the law for a period of time before coming into compliance. In this instance, CMP would eliminate or reduce the profit derived from the violative activity... (Emphasis added.)

While the example is useful, the word "situations" should be followed by the proviso, "where it is necessary to take the profit out of knowing violations." This qualification would make it clear that this approach, i.e., CMP action after corrections made, is only acceptable in cases where it is necessary to effect a remedial goal.

The second suggestion of punitive use appears on page 4 of the Decision Tree document. A statement reads, "Only in rare and compelling cases should a CMP be initiated without prior warning." As an initial matter, HIMA believes the FDA should not initiate a civil penalty action without prior notice; otherwise, a firm does not have an opportunity to take remedial action to cure violations first. Having said this, the phrase "rare and compelling" is overly broad and needs clarification and limitation. In the Application document, on page 3, there is a similar discussion with respect to using civil money penalties for 510(k) violations. The Draft Guidance states, "Prior warning of this violative activity must be documented in accordance with Agency policy unless the violations represent a danger to health or are egregious in nature." Again, contrary to HIMA's view, this statement implies that a civil penalty should be assessed, without notice of violation and an opportunity to cure, in some cases. Having said this, the terms "danger

to health" and "egregious" are not defined for purposes of deciding when it is acceptable not to document prior warning.

G. FDA Draft Civil Money Penalty Reduction Policy for Small Entities, Published in May 18, 1999 *Federal Register*, Should be Accounted for in Draft Guidance

The FDA has published in the *Federal Register* a Draft Civil Money Penalty Reduction Policy for Small Entities (small entity policy). See 64 Fed. Reg. 26984-86 (May 18, 1999). This Agency-wide policy has been modeled after the Presidential Memorandum of April 21, 1995, and Section 223 of the Small Business Regulatory Enforcement Fairness Act (SBREFA), P. L. No. 104-121, 110 Stat. 862 (1996), 5 U.S.C. § 601 note (1996). It is intended to apply to, among other things, device civil penalties authorized under Section 303(f) of the FFDCA, 21 U.S.C. § 333(f). Presently, the Draft Guidance only references the Presidential Memorandum and SBREFA (not explaining their impact in detail) and does not reference the small entity policy.

At several points in the Draft Guidance, the FDA refers to "small businesses," and the Table of Size Standards for various industries which can be used to determine whether a company is a "small business." These references are in the context of penalty reduction and waiver pursuant to the Presidential Memorandum and SBREFA. As HIMA understands it, the Table of Size Standards is only one part of the definition of "small business," and "small business" is only part of the definition of "small entity." HIMA believes the FDA should revise the Draft Guidance to talk in terms of "small entities," as they are the parties eligible for penalty reduction and waiver under the small entity policy. In addition, because the small entity policy, when finalized, will reduce or waive civil penalties already set under the Draft Guidance for device "small entities" in some cases, the Draft Guidance should cross-reference the "to-be-finalized" small entity policy and direct its use and application after a Section 303(f) civil penalty amount is determined against a device "small entity."

At various points throughout the Guidance Document, including pages 1 and 5 of the Decision Tree document, page 2 of the Application document, and page 3 of the Fee Matrix document, the Agency states that FDA staff should take account of monies spent to correct violations for which the penalty is being sought in assessing fines against "small businesses" (which, as discussed above, should be "small entities"). To avoid confusion, the Draft Guidance should make clear that this consideration can be applied to larger firms too. Section 303(f) gives the Agency broad authority to "compromise, modify, or remit, with or without conditions, any civil penalty. . . ." 21 U.S.C. § 333(f)(3)(c). This clarification would help assure that large firms also receive the financial benefit of effecting corrective action.

HIMA's Specific Comments on the Application Document

A. Addition to Scope of the Document

The Application document on page 1 states, "This policy outlines the use of CMP for GMP and premarket notification [510(k)] violations, for chronic and repeat violators, and for less significant violations." The document should define "less significant violations," and the criteria it will use in determining whether to institute civil penalties for these types of violations.

B. Additions to Background Section

The Application document on page 1, in addition to referring to Section 303(f) of the FFDCA should also refer to 21 CFR Part 17. Additionally, it should indicate that the 21 CFR Part 17 only address the administrative procedure for assessing a penalty, and the guidance addresses items not developed in the regulation. Specifically, 1) How to determine the amount of the CMP in light of the statutory procedures to be considered, 2) How to interpret the statutory exemptions to the CMP, and 3) How to determine the compliance date.

C. Discussion of Statutory Exclusions Needs Revision

The Application document, on page 1, describes the various types of violations that Section 303(f) of the FFDCA excludes from the civil money penalty authority. While the text of the Application document generally gives an accurate description of the exclusions found in the statute, HIMA takes issue with one of the text's descriptions. The text says that one of the exclusions from civil penalties is for "[f]ilth violations in devices that are not otherwise defective." The statute makes an exclusion for all device violations under 21 U.S.C. § 351(a)(2)(A) where the devices are not defective. There are two types of violations under § 351(a)(2)(A): (1) violations where the device "has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth," or (2) violations where the device has been "prepared, packed, or held under insanitary conditions. . . whereby it may have been rendered injurious to health." Thus violations of both types, (1) and (2), are excluded from civil money penalty authority where the devices are not defective. Therefore, the statement in the Application document that only "filth violations" were covered by the exclusion should be revised to reflect exclusion of all § 351(a)(2)(A) violations where the devices are not defective.

D. Draft Guidance Should be Directed to All CDRH Staff

The Application document begins, at page 1, by stating, "This document is addressed to all FDA Regional and District Directors for the purpose of advising field personnel of this new guidance policy...." This guidance document should be addressed to FDA staff within the Center for

Devices and Radiological Health (CDRH) as well, since civil money penalty recommendations, e.g. where 510(k) issues are involved, may well originate at headquarters as well as in the field.

E. Guidance on GMP Violations Lacks Clarity and Cites an Inappropriate Reference

Regarding GMP[2] violations, the Application document at page 2 states, "CGMP actions should be considered for those situations in which a firm continues to violate the GMP regulations, there is a reasonable probability that the firm will likely produce nonconforming and/or defective finished devices, and seizure or injunction is not appropriate or necessary to bring about corrective action." (Emphasis added.) This is very nebulous guidance, e.g., it does not explain what constitutes "continuing" to violate or when seizure or injunction are not necessary or appropriate (as discussed in Section I above). As discussed above, reference should be made to the actions authorized by Section 518(b) of the FFDCA. Criteria and definitions are necessary for these concepts; otherwise, they will be subject to too much interpretation, leading to inconsistent Agency decisions. Also the application document should use the statutory criteria referred to in Section 303 (F)(1)(B)(i) which specifies that GMP may only be used for "significant or knowing departure" from the CGMP requirements or if there is a risk to public health.

The Application document on page 2 states, "The District should consider action for Situation 1 GMP deficiencies which are the most serious (see C.P. 7382.830), after providing warning, involving the same or closely related GMP deficiency observations." C.P. 7382.830 is dated May 4, 1995. This document predates the Quality System Regulation and the Food and Drug Administration Modernization Act of 1997. Recently the FDA has released the draft Program Guidance Manual: Inspection of Medical Devices 7382.845 for comment. The Application document should not rely on an outdated, soon to be replaced policy to establish the applicability of CMP to significant or knowing departures from the Quality System Regulation. Rather it should reference the final Program Guidance Manual: Inspection of Medical Devices 7382.845 when it becomes final as the source for defining when the quality system violations may be subject to CMP.

Another point that requires revision in the GMP section concerns the "compliance date." The FDA states on page 2 of the Application Document, "The investigator must establish the point at which corrections should have been complete ('compliance date') following the previous violative GMP inspection." According to the FDA, this date could be, among others, the "date established in the firm's response [to a Warning Letter or other prior notice] as to when it plans to have all corrections completed." However, the Draft Guidance goes on to say, "If there is no response, the compliance date should be the date of the Warning Letter or the date

[2] Now that the FDA has replaced its former Good Manufacturing Practice Regulations (GMP) with Quality System Regulations (QSR), HIMA suggests referring to "QSR/GMP" instead of "GMP" in all relevant places in the Draft Guidance.

other prior notice was provided to the firm." HIMA would propose that, in the "no response" scenario, the date should be the expiration of the time period allowed by the FDA for a response.

F. Guidance on Chronic/Repeat Violators Lacks Clarity

There is no clear guidance for determining when a person becomes a "chronic violator" or a "repeat violator." In the "Chronic/Repeat Violator" section of the Application document, the FDA states:

> Chronic violators remain "out of compliance" for at least two inspections. The second and subsequent inspections find that the person has not corrected the violations, either because the person has not attempted to correct or because the attempts have fallen significantly short of the mark. Persons that are repeat violators are those that fluctuate between being "out of compliance" and "in compliance" from one inspection to the next.

HIMA assumes that the FDA contemplates that "chronic violators" are out of compliance for at least two inspections in a row. If this is the case, the FDA should make this point explicitly. Moreover, the statement regarding corrections falling "significantly short of the mark" is nebulous. More specific criteria for inadequate corrective action should be established. Finally, the FDA's statement that "repeat violators are those that fluctuate between being 'out of compliance' and 'in compliance' from one inspection to the next" needs further elaboration. If this language is applied literally, a firm that had a "bad" inspection several years ago and a "good" inspection recently could still be deemed a "repeat violator" if it is found not in compliance several years from now, even if the non-compliance is for a completely different reason. This result seems unduly harsh. Given the importance of these definitions in determining candidates for civil penalties, it is only fair that the Agency establish more definitive and clear criteria for chronic and repeat violators.

G. Section on Violations of Premarket Notification Requirements Needs to be Clarified

The section of the Application document dealing with Premarket Notification [Section 510(k)] at pages 3-4 needs to be clarified. First, it is not clear why this section is limited to 510(k) violations. In addition to those devices that require premarket notification under Section 510(k), there are Class III devices that require premarket approval under Section 515 of the FFDCA. This section should provide a broader statement of coverage. Moreover, this section states on page 3, "Unless exempted, 510(k) clearance is required, in accordance with 21 C.F.R. 807.81." This language should be clarified to explicitly reference 510(k)-exempt and "grandfathered" pre-amendment devices as not requiring premarket notification.

In the second paragraph of page 4 of the Application document, it states, "CMP may be used even when the firm ultimately obtained 510(k) clearance after receipt of Agency prior notice if the firm shipped articles after prior notice but before obtaining the clearance(s)." This statement does not account for the Agency's exercise of enforcement discretion, which often takes place in these instances. Assume that a firm has made a change to a product that the FDA, after the fact, believes calls for a new 510(k) clearance. The company then submits a new 510(k). The FDA often informally allows the firm to continue to market pending 510(k) clearance through the exercise of enforcement discretion (unless or until a "not substantially equivalent" order issues). The Draft Guidance must address this common circumstance and explain that CMPs are not appropriate under circumstances where enforcement discretion is exercised.

H. Degree of Culpability in Statutory Factors Need to be Expanded

This section should include consideration of factors such as a firm's voluntary willingness to work with the Agency (especially in areas where FDA policy is unclear) or handling devices which represent a public health concern (e.g. the only available device or devices representing significant improvement over similarly marketed devices).

HIMA's Specific Comments on the Fee Matrix Document

A. The Point System Should be Modified

In the table on page 2 of the Fee Matrix document, there is a list of the nine statutory factors -- nature, circumstances, extent, gravity, ability to pay, effect on continued business, history of prior violations, degree of culpability and other factors as justice may require. Each factor has points assigned to it at a low and high level. At the low level, each factor has 1 or 2 points assigned (depending on the factor) and, at the high level, 3 or 6 points assigned (depending on the factor). There appears to be no rationale for the scoring. As exemplified by, "History of Prior Violations," a firm with no prior violations gets a score of at least 2 when in fact a zero is appropriate. HIMA would suggest that Agency officials be allowed to use all numbers between the highest and the lowest levels, and the lowest level should be zero. If the purpose of the point system is to arrive at a point total that will show the "overall violation significance," then the Agency staff should not be forced to choose, on each factor, between the high and the low range. This is particularly needed for those factors -- extent, gravity, and history of prior violations -- where the spread between the low range and the high range is from 2 to 6 points. If the staff can use numbers between these two extremes, the result may be a more fair overall evaluation of the significance of the violation. Additionally the Agency should provide specific examples relating to the numbers pertaining to each factor and explain the basis for why the number is appropriate rather than arbitrary.

The factor, "Degree of Culpability" should allow for a minus figure for firms that acted responsibly under the circumstances.

B. Fee Matrix Document Needs Clarification

On page 3 of the Fee Matrix document, as well as at page 5 of the Decision Tree document, the FDA states "The penalty should be modified or waived only if the firm has made a good faith prompt effort to comply; compliance has been achieved; if there is no significant threat to the public health; and if the monies spent have been carefully, thoroughly, and specifically documented for each compliance activity." Given the importance of possible penalty reductions or waivers, the FDA should more explicitly define what constitutes "good faith" and "no significant threat to the public health" in this context.

HIMA appreciates the opportunity to comment on the Draft Guidance.

Respectfully submitted,

Nancy Singer

Nancy Singer
Special Counsel